REMARKS

The Non-Final Office Action mailed October 26, 2009, has been received and reviewed. Prior to the present communication, claims 1-6, 8, 9, 11-14, 16-18, 20-23, 25-31, 33-40, and 42-51 were pending in the subject application. All pending claims stand rejected under 35 U.S.C. § 103(a). Each of claims 1, 18, and 35 has been amended herein, while no claims have been canceled or added. As such, claims 1-6, 8, 9, 11-14, 16-18, 20-23, 25-31, 33-40, and 42-51 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Rejections based on 35 U.S.C. § 103

A.) Unpatentable Rejection Over U.S. Publication No. 2002/0110823 to Hogan.

Claims 1-6, 11-14, 16, 18, 20-23, 27-31, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0110823 to Hogan (hereinafter Hogan). As the Hogan reference and knowledge of one of ordinary skill in the art at the time of invention, whether taken alone or in combination, fail to teach or suggest all of the elements of independent claims 1 and 18, as amended hereinabove, Applicants respectfully consider this rejection overcome, as hereinafter set forth.

Independent claim 1, as amended hereinabove, recites a computer-implemented method for displaying a warning that a clinical agent received from a clinician should not be administered to a person, wherein the method includes the following step: "initially receiving from a clinician clinical agent information, the clinical agent information including an identifier of a specific clinical agent and a dosage of the specific clinical agent," where "receiving includes

receiving a selection of an entry in a listing of clinical agents on a graphical user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry" (emphasis added).

In this way, a specific entry screen is used to provide the clinical agent information. In particular, the entry screen exhibits intelligence to display the recommended dosage ranges (for selection by a clinician) that correspond with the selected clinical agent. Support for this amendment may be found in the Specification, for example, at paragraphs [0032] – [0034].

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[1] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[2] When determining whether a claim limitation is taught, "All words in a claim must be considered in judging the patentability of that claim against the prior art."[3] Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."[4]

The Office indicates that Hogan implies the clinician will initially determine the clinical agents and dosage used in a particular procedure and compare them against the charts of

[1] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[2] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[3] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).
[4] *Ex parte Clapp*, 227 USPQ 972, 972 (Bd. Pat. App. & Inter. 1985); *see also* MPEP §706.02(j) and §2142.

FIGS. 4 or 5 in the Specification of Hogan.[5] However, the Hogan reference does not consider using a specific clinical agent and a particular dosage to begin the process of determining whether problematic interactions exist. Instead, Hogan begins its process by providing an assay for detecting two or more genetic markers, and, based on the results, selecting an operative course of action.[6] That is, the Hogan reference considers the operative course of action (e.g., clinical agents) only when a genetic marker is detected.

In contrast, the claimed invention schedules a genetic test (e.g., assay for detecting two or more genetic markers) of the patient only when a clinical agent is identified as likely to interact with genes and result in an atypical clinical event. As such, because Hogan is not concerned about the operative course of action unless a genetic marker is detected, Hogan does not inherently consider "*initially* receiving from a clinician clinical agent information" (emphasis added), which includes an "identifier of a specific clinical agent and a dosage of the specific clinical agent," at a GUI.

A fortiori, the Hogan reference does not consider a GUI with the format indicated in claim 1 as amended. In fact, none of the cited portions of Hogan point to a procedure for entering a clinical agent information into a GUI, let alone entering an identifier of a specific clinical agent and a dosage of the specific clinical agent into a GUI that is configured as claimed.

Further, claim 1 is amended to recited the following method steps: "automatically obtaining a genetic test result value for the associated gene of a person [when a gene is associated with the clinical agent];" "comparing the genetic test result value to the second data set [when the patient information comprises the genetic test result value for the associated gene of a person];" and "otherwise, performing the following procedure: (a) *seeking a clinician's*

[5] *See also* Hogan at ¶¶ [0007] – [0009].
[6] *Id.* at ¶¶ [0012] – [0015].

authorization for a test by presenting a genetic test ordering window; and (b) automatically ordering the test to determine the genetic test result value for the associated gene of a person when the test is available and the authorization is granted by a clinician at the genetic test ordering window" (emphasis added).

In this way, the administration of a test on a patient to ascertain a genetic test result value is conditioned on the following four recited criteria: (a) determining that a gene is associated with the clinical agent, (b) determining that patient information in an EMR does not comprise a genetic test result value for the associated gene, (c) determining the test is available, and (d) determining the test is authorized by a clinician via an "ordering window."

The Hogan reference does not describe administering a test on the patient to gather a genetic test result value only after the criteria (a)-(d) have been met. Instead, the Hogan reference initially applies an assay to the tissue sample to generate a genomic profile (i.e., genetic test) without explicit consideration of whether a particular gene is associated with a clinical agent involved in a medical procedure. Further, the Hogan reference does not explicitly describe exploring a patient EMR prior to approving the application of an assay to a tissue sample. Moreover, Hogan does not consider an "ordering window" in which a clinician may authorize the administration of a test on a patient.

Each and every one of the four criteria for administering a test to gather a genetic test result value are not explicitly stated or inherently considered by Hogan. Specifically, the process of the Hogan reference involves the following steps performed in the order that they are listed: (1) attain a tissue sample, (2) apply an assay to the tissue sample to generate a genomic profile, (3) detect variant alleles of genes from the genomic profile, and (4) rely on the clinician

to adjust a surgical procedure based on the variant alleles.[7] As such, because the processes of Hogan rely first and foremost on creating a genomic profile from the application of the assay, conditions on when/if to order the assay are not implicit in the cited portions of the Hogan reference.

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claim 1 be withdrawn. Further, claim 1 is believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 2-6, 11-14, and 16 depend, either directly or indirectly, from independent claim 1. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[8]

Independent claim 18, as amended herein, recites a computer system for displaying a warning that a clinical agent received from a clinician should not be administered to a person, where the computer system includes a "third determining component" and a "displaying component." The third determining component performs a procedure comprising: "(a) incident to determining that the genetic test result value correlates to one or more of the one or more polymorphism values, accessing the second data set; (b) utilizing the second data set to determine whether a risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent, and (c) *indicating a lower dosage of the clinical agent be prescribed when the risk of damage is less than not administering the clinical agent*" (emphasis added).

In this way, there is a specific determination of whether "a risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent," which is only conducted after the determination of whether the genetic test

[7] *Id.* at ¶¶ [0015] – [0019].

result value correlates to one or more of the one or more polymorphism values is positive. Support for this amendment may be found in the Specification, for example, at paragraphs [0046], [0052] – [0054], and at Table 2 in paragraph [0044] that represents the "second data set."

The Examiner indicates that Hogan discusses assessing the dosages associated with clinical agents at paragraphs [0005], [0008], and [0138]. In particular, Hogan discloses the following: "Complications can be avoided by substituting other medications or adjusting dosage."[9] However, Hogan does not consider the very specific risk-analysis determination recited above in claim 18, which is made by the third determining component. That is, a general statement of adjusting a dosage to avoid complications that may result from adverse reactions to certain drugs does not render obvious each and every word of the positively recited method steps (a) – (c) above.

Further, amended claim 18 recites a "displaying component" that performs a procedure comprising: "(a) receiving an indication from the third determining component that the risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent; and (b) displaying in a notification window a warning to the clinician that the clinical agent should not be administered to the person," where "the notification window surfaces a selectable area for accessing information regarding the one or more of the polymorphism values, and wherein the notification window displays an alternative clinical agent that does not correlate with the genetic test result value." In this way, the displaying component issues a warning on a notification window upon the condition of the "risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent." Also, the notification window is configured to present to a user two specific items: (a) a selectable area for accessing

[8] *See* 37 C.F.R. § 1.75(c) (2006).
[9] Hogan at ¶ [0008].

information regarding polymorphism values, and (b) an alternative clinical agent that does not correlate with the genetic test result value.

The Office indicates that the Hogan reference at paragraph [0190] teaches risk assessment for various treatment options are displayed to a clinician, and at paragraphs [0189] – [0193] teaches the use of computers for performing the instant invention. Further, the Office indicates that these general disclosures of computers imply the specific steps of claimed in claim 18.[10] However, these cited portions of the Hogan reference do not teach the very specific notification window that concomitantly displays the items (a) and (b) listed immediately above. Instead, the general discussion of Hogan at paragraph [0190] describes displaying the genomic profile in a suitable format. This genomic profile is raw data, while the notification window of the claimed invention displays "alternative clinical agents" that are selected via analysis of the entered clinical agents, the associated genes, and the polymorphism values and the genetic test result values of a patient. Because the type of information being displayed in the Hogan reference is very distinct from the type of information being displayed in the notification window of claim 18, the disclosure of Hogan cannot be considered to imply the claimed configuration of the notification window of claim 18.

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claim 18 be withdrawn. Further, claim 18 is believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 20-23, 27-31, and 33 depend, either directly or indirectly, from independent claim 18. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[11]

[10] Office Action at pg. 8, ll. 8-16.
[11] *See* 37 C.F.R. § 1.75(c) (2006).

B.) Unpatentable Rejection Over Hogan in further view of U.S. Patent No. 6,219,674 to Classen.

Claims 35-40 and 44-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hogan in further view of U.S. Patent No. 6,219,674 to Classen (hereinafter Classen). As the Hogan reference and the Classen reference, whether taken alone or in combination, fail to teach or suggest all of the elements of independent claims 1 and 18, as amended hereinabove, Applicants respectfully consider this rejection overcome, as hereinafter set forth.

Independent claim 35, as amended hereinabove, recites a computer-readable medium containing instructions for controlling a computer system for displaying a warning that a clinical agent received from a clinician should not be administered to a person. The process of controlling includes the step of, upon determining that the "genetic test result value" cannot be obtained from the EMR, "calculating the likelihood that the person displays a genetic mutation linked to the gene associated with the clinical agent based on genetic variability of the gene within the general population."

In this way, an EMR of the person (e.g. patient in a hospital) lacks complete information and there is an assumption that the EMR likely lacks demographic information of the person as well. Support for this amendment may be found in the Specification, for example, at paragraphs [0040] – [0042].

The Examiner concedes that the primary reference, Hogan, does not teach the recited step of calculating a risk of expressing a genetic variability by exploring the existence of the genetic variability of a gene within the general population. Classen does not cure Hogan, as

Classen does not consider determining a genetic variability of the gene within the general population to ascertain whether to administer a test. Instead,

The Office concedes that the primary reference, Hogan, does not explicitly teach the step of using genetic variability of the gene within the general population to calculate the likelihood that a person displays a genetic mutation. However, the Office contends that Classen teaches that extracted data can be analyzed to calculate risk for an individual, where the analyzed data pertains to persons with similar characteristics (e.g., race, age, and gender).[12]

Classen, as cited, does not teach using genetic variability of the gene within the *general population* to calculate the likelihood that a person displays a genetic mutation. Instead, the Classen reference describes using demographic information of a patient to access statistically relevant information of a "subgroup" in which the patient is a member. In other words, Classen describes inspecting an "adverse event database" before exposing a medical product to a patient by searching the database with demographic information from the patient.[13] Accordingly, the cited portions of the Classen reference do not account for a situation where demographic information is unavailable such that a subgroup of the patient cannot be determined. Moreover, the cited portions of the Classen reference do not describe or suggest using the "genetic variability of the gene within the general population to calculate the likelihood that a person displays a genetic mutation." Accordingly, the Classen reference fails to cure the stated deficiencies of the primary reference, Hogan.

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claim 35 be withdrawn. Further, claim 35 is believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 36-40 and 44-50

[12] Office Action at pg. 14, ll. 19-22.
[13] *See* Classen cols. 5 and 6.

depend, either directly or indirectly, from independent claim 35. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[14]

Further, claim 35 recites the feature of "*constructing a message* to communicate the calculated likelihood of the genetic mutation and any atypical clinical events that are associated therewith." The Office indicates that the primary reference, Hogan, does not explicitly teach this feature. However, the Office does not cite to a reference that does teach this feature of "constructing a message" to communicate the information above. Accordingly, for at least this reason, a *prima facie* case of obviousness is not properly set forth by the Office, and, as a matter of law, the § 103(a) rejection of claim 35, and claims that depending therefrom, must be withdrawn.

[14] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, each of claims 1-6, 8, 9, 11-14, 16-18, 20-23, 25-31, 33-40, and 42-51 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

A One Month Extension of Time is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.114070.

Respectfully submitted,

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